



## **FEDERAL TRADE COMMISSION**

**[File No. 211 0184; Docket No. C-4763]**

### **Medtronic/Intersect ENT; Analysis of Agreement Containing Consent Orders to Aid Public Comment**

**AGENCY:** Federal Trade Commission.

**ACTION:** Proposed consent agreement; request for comment.

**SUMMARY:** The consent agreement in this matter settles alleged violations of federal law prohibiting unfair methods of competition. The attached Analysis of Proposed Consent Orders to Aid Public Comment describes both the allegations in the complaint and the terms of the consent orders—embodied in the consent agreement—that would settle these allegations.

**DATES:** Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY**

**INFORMATION** section below. Please write: “Medtronic/Intersect ENT; Docket No. C-4763” on your comment and file your comment online at <https://www.regulations.gov> by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580.

**FOR FURTHER INFORMATION CONTACT:** Charles Dickinson (202-326-2617), Bureau of Competition, Federal Trade Commission, 400 7th Street SW, Washington, DC 20024.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis of Agreement Containing Consent Orders to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Website at this web address: <https://www.ftc.gov/news-events/commission-actions>.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Write “Medtronic/Intersect ENT; Docket No. C-4763” on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the <https://www.regulations.gov> website.

Due to protective actions in response to the COVID-19 pandemic and the agency’s heightened security screening, postal mail addressed to the Commission will be delayed. We strongly encourage you to submit your comments online through the <https://www.regulations.gov> website.

If you prefer to file your comment on paper, write “Medtronic/Intersect ENT; Docket No. C-4763” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC-5610 (Annex D), Washington, DC 20580.

Because your comment will be placed on the publicly accessible website at <https://www.regulations.gov>, you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment

should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on <https://www.regulations.gov> – as legally required by FTC Rule 4.9(b) – we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC Website at <https://www.ftc.gov> to read this Notice and the news release describing this matter. The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments it

receives on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <https://www.ftc.gov/site-information/privacy-policy>.

## **Analysis of Agreement Containing Consent Orders to Aid Public Comment**

### **I. Introduction**

The Federal Trade Commission (“Commission”) has accepted for public comment, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Medtronic plc, Medtronic, Inc. (“Medtronic”), and Intersect ENT, Inc. (“Intersect”) (together, “Respondents”). The Consent Agreement is designed to remedy the anticompetitive effects that otherwise would result from Medtronic’s acquisition of Intersect.

Pursuant to an Agreement and Plan of Merger dated as of August 6, 2021, Medtronic proposes to acquire all of the issued and outstanding securities of Intersect for approximately \$1.1 billion (the “Acquisition”). The Commission’s Complaint alleges that the Acquisition violated Section 7 of the Clayton Act, as amended, 15 U.S.C. 18, and that the Acquisition agreement constitutes a violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. 45, by substantially lessening competition in the U.S. markets for balloon sinus dilation products and ear, nose, and throat (“ENT”) navigation systems.

The proposed Decision and Order (“Order”) contained in the Consent Agreement requires Respondents to divest to Hemostasis, LLC (“Hemostasis”) the assets and business of Intersect’s subsidiary Fiagon AG Medical Technologies (“Fiagon”). Respondents must complete the transfer no later than 10 days after Medtronic consummates its acquisition of Intersect. The Commission has issued, and Respondents have agreed to comply with, an Order to Maintain Assets that requires Respondents to

operate and maintain the divestiture assets in the normal course of business through the date the approved buyer acquires the divested assets.

The Commission has placed the Consent Agreement on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the comments received and decide whether it should withdraw, modify, or make the proposed Order final.

## **II. The Relevant Market and Competitive Effects**

The Commission's Complaint alleges that the relevant product markets in which to analyze the Acquisition are the research, development, licensing, manufacturing, marketing, distribution, and sale of (a) balloon sinus dilation products and (b) ENT navigation systems. Balloon sinus dilation products are catheter devices used to clear blocked sinuses in patients suffering from chronic rhinosinusitis. ENT navigation systems allow physicians to view and track the location of operating instruments such as balloon sinus dilation products during sinus surgery.

The relevant geographic market in which to analyze the competitive effects of the Acquisition is the United States. Balloon sinus dilation products and ENT navigation systems are medical devices subject to approval by the U.S. Food and Drug Administration before sale in the United States. As such, medical devices not approved for sale in the United States do not provide competitive alternatives for U.S. consumers.

The Acquisition would likely substantially lessen competition in the relevant markets. The U.S. markets for balloon sinus dilation products and ENT navigation systems are both highly concentrated. The Acquisition, if consummated, would reduce the number of independent manufacturers of balloon sinus dilation products from four to three. Fiagon, having just entered the U.S. market in 2021 after securing regulatory approvals for its balloon sinus dilation products, is poised to become an important

competitive constraint on the established ENT market leaders, including Medtronic. In ENT navigation systems, Medtronic currently holds a dominant position, and the Acquisition would eliminate a nascent competitive threat in Fiagon.

### **III. The Proposed Order and the Order to Maintain Assets**

The proposed Order and the Order to Maintain Assets would remedy the Acquisition's likely anticompetitive effects by requiring Respondents to divest the entirety of the Fiagon business and assets to Hemostasis. Hemostasis is an established participant in the ENT medical device segment and has the expertise, sales infrastructure, and resources to restore the competition that otherwise would have been lost pursuant to the Acquisition. The parties must divest all facilities and equipment, intellectual property, business information, and other assets used with and related to the Fiagon business. Hemostasis also intends to retain Fiagon employees. Because Hemostasis will acquire all assets related to the Fiagon business, and the parties are required to obtain all third-party consents before the divestiture transaction is consummated, Hemostasis will be able to begin manufacturing its own supply of ENT navigation systems and balloon sinus dilation products from day one.

The proposed Order contains additional provisions designed to ensure the effectiveness of the relief. For example, the proposed Order requires the Respondents to assist and cooperate in the defense against any intellectual property litigation related to the Fiagon assets. Respondents are required to provide Hemostasis with transition assistance for up to one year following the divestiture of the assets and must cooperate with and assist Hemostasis to evaluate and offer employment to employees involved in the business and assets subject to divestiture. Respondents have also agreed not to enforce any employee noncompete or confidentiality agreements against Hemostasis relating to employees that interview or accept employment with Hemostasis. The proposed Order and the Order to Maintain Assets further require Medtronic to operate

and maintain the divestiture assets in the ordinary course of business, including maintaining the economic viability, marketability, and competitiveness of the Fiagon business until the divestiture transaction takes place.

The Commission will appoint Jeryl Hilleman to act as an independent Monitor to oversee the Respondents' compliance with the requirements of the Order, and to keep the Commission informed about the status of the transfer of the Fiagon business to Hemostasis. The proposed Order requires that the divestiture to Hemostasis be completed no later than 10 days after Medtronic consummates the Acquisition.

In addition to requiring the divestiture of the Fiagon assets and business, the proposed Order requires Respondents to obtain prior approval from the Commission before making certain future acquisitions in the relevant markets for a period of ten years from the date the Order is issued. The proposed Order also requires Hemostasis to obtain prior approval from the Commission before transferring any of the divested assets to any buyer for the first three years after Hemostasis acquires the divestiture assets. For the seven years following the initial three-year period, the proposed Order requires Hemostasis to obtain prior approval from the Commission before transferring any of the divested assets to any buyer engaged in the research, development, manufacture, marketing, or sale of any balloon sinus dilation products or ENT navigation systems.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and the Commission does not intend this analysis to constitute an official interpretation of the proposed Order or to modify its terms in any way.

By direction of the Commission.

**April J. Tabor,**

*Secretary.*

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